PTO/SB/17 (01-03)
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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 145.00

Complete if Known	
Application Number	09/676,783
Filing Date	October 2, 2000
First Named Inventor	William J. McBride et al.
Examiner Name	WESSENDORF, Teresa D.
Art Unit	1639
Attorney Docket No.	40923-0065US2

METHOD OF PAYMENT (check one)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: 08-1641 (Docket No. 40923-0065US2)

Deposit Account Name: Heller Ehrman White & McAuliffe LLP

The Commissioner is authorized to: *(check all that apply)*

☒ Charge fee(s) indicated below ☐ Credit any overpayments

☐ Charge any additional fee(s) during the pendency of this application

☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Fee Code	Entity Fee ($)	Small Fee Code	Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

			Extra Claims		Fee from below		Fee Paid
Total Claims		-20** =		x		=	
Independent Claims		-3** =		x		=	
Multiple Dependent						=	

Large Fee Code	Entity Fee ($)	Small Fee Code	Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	**Reissue independent claims over original patent
1205	18	2205	9	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

***or number previously paid, if greater; For Reissues, see above*

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Fee Code	Entity Fee ($)	Small Fee Code	Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	145
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)_____

* Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 145.00

SUBMITTED BY					Complete *(if applicable)*
Name *(Print/Type)*	Patricia D. Granados	Registration No. *(Attorney/Agent)*	33,683	*Telephone*	202-912-2000
Signature	Patricia D. Granados	*Date*	May 10, 2004	Customer No. 26633	

PTO/SB/32 (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

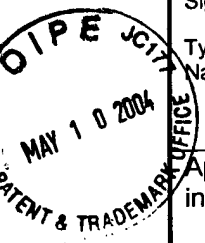
REQUEST FOR ORAL HEARING BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Docket Number (Optional)
40923-0065US2

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Assistant Commissioner for Patents, Washington D.C. 20231" on _____.

Signature _____

Typed or printed Name _____



In re Application of
William J. McBride et al.

Application Number	Filed
09/676,783	October 2, 2000

For
RADIOMETAL-BINDING PEPTIDE ANALOGUES

Group Art Unit	Examiner
1639	WESSENDORF, Teresa D.

Applicant hereby requests an oral hearing before the Board of Patent Appeals and Interferences from in the appeal of the above-identified application.

The fee for this Request for Oral Hearing is (37 CFR 1.17(d)) $ 290.00.

☒ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by half, and the resulting fee is: $ 145.00.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Commissioner has already been authorized to charge fees in this application to a Deposit Account. I have enclosed a duplicate copy of this sheet.

☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 08-1641 . I have enclosed a duplicate copy of this sheet.

☐ A petition for an extension of time under 37 CFR 1.136(b) (PTO/SB/23) is enclosed.
For extensions of time in reexamination proceedings, see 37 CFR 1.550(c).

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

☐ attorney or agent of record.

☒ attorney or agent acting under 37 CFR 1.34(a).
Registration number if acting under 37 CFR 1.34(a). 33,683.

Patricia D. Granados
Signature

Patricia D. Granados
Typed or printed name

5/10/04
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.

05/11/2004 EFLORES 00000103 081641 09676783

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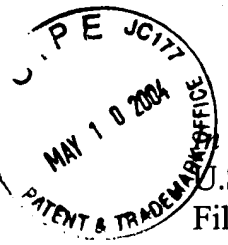
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES



In re Application of McBride and Griffiths
U.S. Serial No.: 09/676,783
Filed: October 2, 2000
Attorney Docket No.: 40923-0065US2 (formerly 018733/0997)
For: RADIOMETAL-BINDING PEPTIDE ANALOGUES

REPLY

Appeal from Group 1639

HELLER EHRMAN WHITE & McAULIFFE LLP
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This is in reply to the Examiner's Answer mailed March 10, 2004 (Paper No. 11). Appellants do not believe that any fees are due; in the event this is not correct, the Board is authorized to debit the undersigned's account no. 08-1641.

I. THE EXAMINER'S POSITION

A. The Examiner's Rejection

The Examiner acknowledges that claims 24-40 and 42-43 meet the statutory requirement for enablement and utility. (Examiner's Answer, page 5, Section 11, first paragraph.) However, the Examiner alleges that these same claims fail to meet the written description requirement because there is not "enough written description in the specification as to the different kind of tumor(s), peptides, modes of administration, dosage and test procedures or steps in specific terms as to the treatment method." (Examiner's Answer, page 4, Section 10, third paragraph.)

The Examiner states that the specification describes "an assay method as to the supposed binding effect of the peptide LHRH or VIP analogues to breast cancer cells" (*Id.*), but alleges that no results are provided for the binding method, that it is not apparent how the assay method translates or correlates the binding effect to a treatment method and that claim 24 does not recite the peptides LHR or VIP analogues. According to the Examiner, this alleged "general statement" and "general assay method" fail to satisfy the statutory requirement for a full, clear and concise description of the claimed method. (Examiner's Answer, page 5, Section 10, last paragraph.)

B. The Examiner's Opinion

In view of the above, it appears that the Examiner's written description rejection is based upon the Examiner's belief that the claimed invention is not described "enough" or is not described "clearly" or "fully" or "concisely." However, the Examiner's true concern is a public policy one, which is clear from the following:

> To allow appellants to dominate a highly unpredictable and not fully elucidated field based on the expediency of the prophetic, generalized statement or meaningless conclusion in the specification will not promote science as intended by the law. It will bar one who has actually worked and discovered the details of the treatment method.

(Examiner's Answer, page 15, next to last paragraph)

Appellants respectfully submit that such concerns are misplaced.

II. THE LAW

The controlling law in this case is well-settled. First, there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed. *In re Wertheim*, 541 F. 2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). In order to meet the written description requirement, there must be sufficient written description to inform a skilled artisan that the applicant was in possession of the invention as a whole at the time the application was filed. *See e.g. Purdue Pharma L.P. v. Faulding Inc.* 230 F. 3d 1320,1323, 56

USPQ 2d 1481, 1483 (Fed Cir. 2000); *as cited in Manual of Patent Examining Procedure* ("MPEP"), Section 2163, page 2100-165. (Rev. 1 Feb. 2003).

It does not matter that the description in the specification is prophetic. It does not matter that the claim is to a genus and only a few species are exemplified. It does not matter that applicants rely upon what is known in the art to describe the invention. It does not matter that the result is a claim that dominates others. It does not matter that others may continue research in the field of the invention and reduce to practice or discover embodiments covered by the claims. It does not matter that the Examiner does not approve of this state of the law or is concerned about the promotion of science. What matters is that the specification conveys to those of skill in the art that they were in possession of the invention.

Possession of an invention can be shown in many ways. MPEP at 2100-165. For instance, it is proper to rely upon what is already known in the art. The description need only describe in detail that which is new or not conventional. *See Hybritech v. Monoclonal Antibodies*, 802 F. 2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).

III. THE APPLICATION OF LAW TO FACTS

Although the controlling law is well-settled, any written description inquiry is driven by the facts of an individual case. These facts include what is in the specification as well as what was known in the art at the time of the invention.

During the course of this appeal, the Examiner agreed to allow claims directed to a method of treating a tumor so long as peptides were limited to LHRH, SMS, VIP and MSH. Thus, the Examiner has conceded that the facts of this case - including the *in vitro* assays in the specification and the art relied upon in appellants' brief - show that appellants were in possession of an invention directed to a method of treating tumors, at the time of the invention. The Examiner did not challenge the correlation of the binding with the efficacy of treatment, did not question the extrapolation of *in vitro* data to *in vivo* efficacy, and did not demand explicit modes of administration, as she does now in the Examiner's Answer. Appellants declined the Examiner's offer because the evidence presented to show possession of the invention considered allowable is the same evidence that supports a claim of broader scope. Appellants believed then and believe now that the Examiner's position is insupportable.

Appellants remind the Examiner that the present claims are directed to a method of treating tumors based upon the discovery of a new method of radiolabeling peptides. The peptides, *per se*, are not the point of novelty, but rather the novel method of labeling them for a therapeutic use. The Examiner has conceded in the Examiner's Answer that appellants have taught how to make and use the generic invention (enablement) and that such generic invention is useful (utility). Thus, the Examiner does not challenge the detail by which appellants teach how to make or how to use the generic invention in the specification or

challenge the operability of the generic invention. Nevertheless, in the Examiner's Answer, the Examiner refused to give weight to the teachings of numerous articles related to the use of radionuclides for tumor therapy and cited to support the sufficiency of appellants' written description. Rather, the Examiner challenged the significance of their teachings or the sufficiency of the presented data. The Examiner's dismissal of the cited references is a simply improper and inconsistent with the Examiner's position with regard to enablement and utility.

IV. CONCLUSION

The Examiner's position in this case as reflected in the Examiner's Answer is improper and based upon a selective application of the law and a selective reading of the record. Accordingly, reversal of the rejection for lack of written description is proper and respectfully requested.

Respectfully submitted,

Date May 10, 2004

By Patricia D. Granados

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